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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,784

01/26/2006

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LARSSON4

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

05/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/542,784

Applicant(s)

LARSSON ET AL.

Examiner

Michael Szperka

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) 25-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-24 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/18/06</u>   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Applicant's response received March 7, 2007 is acknowledged.  
Claims 1-19 have been canceled.  
Claims 20-39 are pending in the instant application.

Applicant's election with traverse of Group I, claims 20-24 and 39, drawn to compositions comprising avian antibodies that bind *Enterobacter cloacae* in the reply filed on March 7, 2007 is acknowledged. The traversal is on two grounds. The first is that the instant inventions enjoy unity of invention because the cited art of Coleman et al. (WO 98/14209, of record) does not anticipate the instant invention because they do not teach avian antibodies that bind *E. cloacae*.

This argument is not persuasive because the breadth of applicant's claimed invention is not limited to *E. cloacae*. In particular, it is noted that with the exception of claim 28, applicant's claimed methods encompass the administration of an avian antibodies that specifically bind any microbial antigen. As detailed in the restriction requirement, Colman et al. teach such methods.

Applicant's second argument is that there is no search burden.

This argument is not persuasive because search burden is not a consideration that is used when making the determination that an application lacks unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 25-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 7, 2007.

### **Information Disclosure Statement**

2. Applicant's IDS form received July 18, 2006 is acknowledged and has been considered.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 20-24 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colman et al. (WO 98/14209, of record) in view of Boccia et al. and in view of Carroll et al. (US Patent 5,599,539).

Colman et al. teach compositions comprising avian antibodies (i.e. IgY) that are to be used to treat enteric infections in immunocompromised patients such as neonates (see entire document, particularly the abstract, lines 1-18 of page 2, and lines 6-32 of page 8). They disclose that passive immunization (i.e. administration of preformed antibodies to a patient) has been shown to protect individuals from neonatal necrotizing enterocolitis (see particularly lines 8-12 of page 6 and lines 24 and 25 of page 9). The avian antibodies are disclosed as being administered in a multitude of forms, including as part of a nutritional formula given to patients in an intensive care unit (see particularly pages 14 and 15, most particularly lines 28-30 of page 15). These teachings differ from the instant claimed invention in that Colman et al. do not disclose that their avian antibodies are specific for antigens found in *E. cloacae*.

Boccia et al. teach that necrotizing enterocolitis is one of the most serious gastrointestinal diseases among newborns, that it mainly affects newborns in intensive

care units, and that *E. cloacae* is an important causative agents for this disease (see entire document, particularly the abstract and Table 3).

Carroll et al. teach that avian antibodies are to be mixed with infant formula for ease of administration to infants (see particularly lines 45-61 of column 3).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the instant invention was made to make a composition comprising IgY that is specific for *E. cloacae*. Motivation to do so comes from the teachings of Boccia et al. that *E. cloacae* is a major pathogen in neonatal intensive care units that causes necrotizing enterocolitis and the teachings of Colman et al. that antigen specific IgY is to be used to treat diseases such as neonatal necrotizing enterocolitis. A skilled artisan would have been further motivated to place the *E. cloacae* specific IgY antibodies into infant formula based on the teachings of Colman et al. that their antibodies are to be added to nutritional supplements given to intensive care patients and the teachings of Carroll et al. that IgY is to be added to infant formula for ease of administration to infants.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 24 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites the limitation "nutritional agent" in line 3. There is insufficient antecedent basis for this limitation in the claim. Specifically, claim 24 depends from claims 20, 21 and 22, none of which recite the limitation "nutritional agent".

Similarly, claim 39 recites "buffering agent", yet the claims from which it depends, namely claims 20, 21 and 23, do not recite this limitation.

Applicant has many options for fixing these antecedent basis problems, such as deleting the terms that lack antecedent basis or including these limitations in earlier

Art Unit: 1644

claims. If applicant chooses to add the limitations to earlier claims, for example adding the limitations "nutritional agent" and "buffering agent" to independent claim 20, the other pending claims should be checked to ensure that they continue to further limit the claimed invention.

### ***Claim Objections***

7. Claim 20 is objected to because it is proper for the scientific names of organisms, such as *Enterobacter cloacae*, to be italicized. Appropriate correction to claim 20 is requested.

### ***Specification***

8. It is noted that the specification and abstract also do not italicize organisms referred to by their scientific names, such as *Enterobacter cloacae*. An example of this can be found on line 8 of page 1 of the instant specification. Appropriate correction is requested.

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Michael Szperka', with a stylized flourish at the end.

Michael Szperka, Ph.D.  
Patent Examiner  
Technology Center 1600  
May 17, 2007